

**SASFORREACH Consortium
Information Letter 8
Synthetic Amorphous Silica EC 231-545-4:
Dossier update 2022**

**URGENT: ACTION REQUIRED FOR REACH-REGISTRATION OF
SYNTHETIC AMORPHOUS SILICA (SAS)**

Dear co-registrants,

The SASforREACH Consortium (“**Consortium**”) would like to inform you about the recent update of the joint registration dossier for synthetic amorphous silica (“**SAS**”) which was submitted to ECHA on 18 October 2022 and passed the technical completeness check in REACH-IT.

Please note that your feedback to this message is needed and crucial to ensure that your forms of SAS are covered by the joint registration dossier. We kindly request you to provide the manager of the Consortium (“Consortium Manager”) with information on your SAS materials. THE INFORMATION PROVIDED BY YOU WILL BE TREATED AS CONFIDENTIAL BUSINESS INFORMATION AND WILL NOT BE DISCLOSED TO THE MEMBERS OF THE CONSORTIUM.

Your feedback is needed for the following reasons:

Consequences of the lead dossier update for the dossiers of member registrants

On October 18, 2022, the lead registrant Evonik Operations GmbH submitted an update of the joint registration dossier for SAS on behalf of the joint submission members. The update introduced the **NEW** boundary composition for a bulk (i.e., a non-nano) form of SAS including a new study data package and a read-across justification.

The dossier now contains the boundary compositions for the following SAS forms:

- Nano-structured SAS Set 1 (untreated) – since 12/2019
- Nano structured SAS Set 2 (treated) – since 12/2019
- Non-nano structured SAS (bulk) – since 10/2022, including
 - Stöber process
 - Wet route process

Therefore, three forms of SAS (bulk and nano) are currently part of the joint submission dossier. We would like to stress that basic data used to establish a nano-structured SAS set 1 (untreated) and a nano-structured SAS set 2 (treated) have been part of the registration dossier since the date of coming into force of REACH. Since 2009 new data on nano-structured SAS were generated to fill and address data gaps for the nanofoms of SAS only.

Therefore, all registrants must check whether their member registration is referring to the correct boundary composition for nano, bulk, or both SAS forms, depending on the products produced and/or imported by the respective co-registrant. We would like to remind co-registrants that according to Implementing Regulation (EU) 2020/1435 the update of the lead dossier triggers a legally binding deadline to update member registrants' registration dossiers within a certain deadline. We would like to stress that without a dossier update the member registration may become non-compliant with Art. 22 REACH, Art. 12, 13 Implementing Regulation (EU) 2020/1435 and actions by ECHA and/or national enforcement authorities may be triggered.

In case of a **nano-form**, member registrants need to update the individual legal entity composition information in their dossier with a reference to the respective boundary composition of the nano-form(s). Furthermore, the individual nano-forms of the registrants need to be described with the respective REACH Annex VI data.

In case of a **bulk-form**, the reference to the newly established bulk boundary composition must be included in the legal entity composition information of the member dossier by submitting a member dossier update. Furthermore, the data according to REACH Annex VI must be conclusive to demonstrate the non-nano structure of the registered forms of the substance. In both cases action by **all** member registrants is needed unless the registrants have already updated their member dossier and established a link to one of the two nano boundary compositions. **Please be aware that any member registration without individual opt-out could not cover a bulk SAS-form before.**

Consequences of ECHA's draft decisions for member registrants' dossiers

The Consortium would also like to inform you about ECHA's draft decisions issued on the SAS Dossier. In the draft decisions dated 20 June 2022 (CCH-D-2114599940-33-01/D; CCH-D-2114599908-21-01/D) ECHA has requested to update the nano boundary composition as well as to provide additional information on the nature of the surface modification as follows:

- Report d10, d50 and d90 values based on the number-based particle size distributions as well as the values of the number fraction of constituent particles.
- Provide a list of all the agents (incl. CAS and EC numbers) used for surface treatment of all the nano-forms or at least a description of the chemical nature of the modified surface.

The Consortium is currently working on an action plan how to compile the requested data from the member registrants to be considered in the next joint registration dossier update. **It is in your own best interest to provide this information to the Consortium Manager because the joint registration dossier can (for obvious reasons) only cover those compositions which are known to the Consortium Manager. We reiterate that it is the responsibility of each registrant to ensure that all forms of the substance manufactured and/or imported in the EEA by such registrant are covered by its registration. In case of very specific SAS forms more actions from you may be required, i.e., the definition of a separate nano-form or set of similar nano-forms.**

Actions required to be taken by member registrants

In order to comply with their REACH obligations, member registrants are called upon to immediately review their company-specific data and provide information to the Consortium Manager. This process will be conducted in two separate steps:

1. In a first step, **all** registrants are hereby requested to **provide feedback on which SAS forms (i.e., bulk or nano) are relevant for their registration. This feedback needs to be provided to the Consortium Manager by December 15, 2022 at the latest.**
2. In a second step, (only) those companies who have registered or need to register **nano-forms of SAS** will be asked to fill in a questionnaire with specific information in order to address ECHA's draft decision.

THE INFORMATION PROVIDED BY YOU WILL BE TREATED AS CONFIDENTIAL BUSINESS INFORMATION AND WILL NOT BE DISCLOSED TO THE MEMBERS OF THE CONSORTIUM.

The Consortium must urgently stress again that your feedback is crucial to define the boundary composition of the nano-forms in the most convenient way for all registrants to ensure that most if not all forms are sufficiently covered. Otherwise, your SAS forms may not be covered by the updated boundary composition. This could result in further actions by ECHA, possibly affecting your registration status and could lead to enforcement actions by ECHA and/or by national authorities and administrative and even criminal consequences.

AS COMPLIANCE WITH THE REACH REGULATION IS THE SOLE RESPONSIBILITY OF EACH REGISTRANT, THE CONSORTIUM DOES NOT ASSUME ANY LIABILITY AND WILL NOT GIVE ANY WARRANTY FOR REACH COMPLIANCE OF ANY JOINT REGISTRANT.

Consortium Member Companies

Albemarle Europe, BASF SE, Cabot Corp., Evonik Operations GmbH, Grace GmbH, IQE S.A., PPG Ind. Inc., PQ Corporation, Rhodia Operations S.A.S., Clariant Produkte (Deutschland) GmbH, Wacker Chemie AG, Zeochem AG, Merck KGaA

Annex I different SAS forms

SAS is typically manufactured as a nano-structured material. Precipitated silica, silica gel, colloidal silica or pyrogenic silica normally fall within the definition of nanoparticles in Annex VI of the REACH Regulation by reason of their internal structure (so-called constituent particles) or by reason of their size.

According to Annex VI of the REACH Regulation, a “nano-form” is a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm (Please see Appendix for nano-forms applicable to the Guidance on Registration and Substance Identification, Version 2.0 – January 2022).

The internal structures form agglomerates and aggregates in the μm or mm size (gel, precipitated or fumed SAS). Colloidal SAS in mono- or poly-dispersed form is present in most cases as particles below 100 nm, colloidal forms with a d50 particle size above 100 nm fall into the bulk-form of SAS; for further information please refer to the latest Q&A on the SASforREACH webpage (www.reach-sas.org). In some rare cases non-colloidal SAS exists also as a non-nanoform (bulk SAS), with constituent particles larger than 100 nm; for further information please also refer to the aforementioned Q&A.

Sample electronic microscopy images provided below illustrate various forms of SAS to provide guidance and help for your determinations. The images do not replace your obligation to generate your own electron microscopy investigations to determine the status for your SAS forms placed on the EU market.

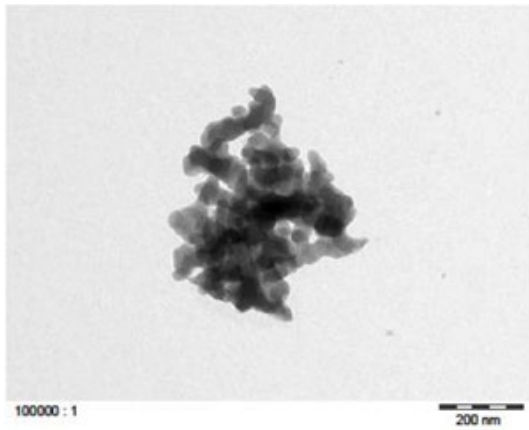


Figure 1: TEM image of a precipitated nano SAS

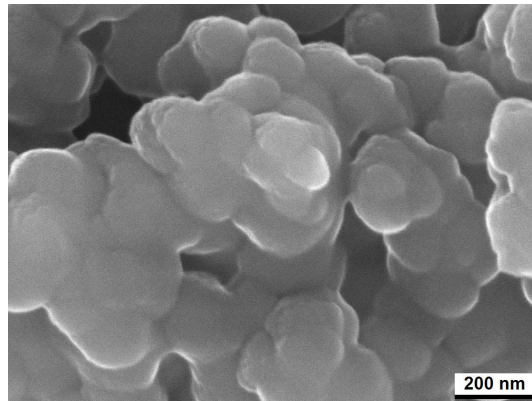


Figure 4: A SEM image of a precipitated bulk SAS

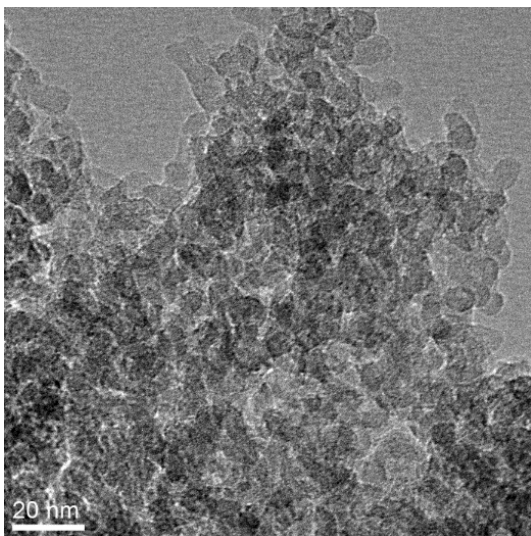


Figure 2: A TEM image of a nano silica gel

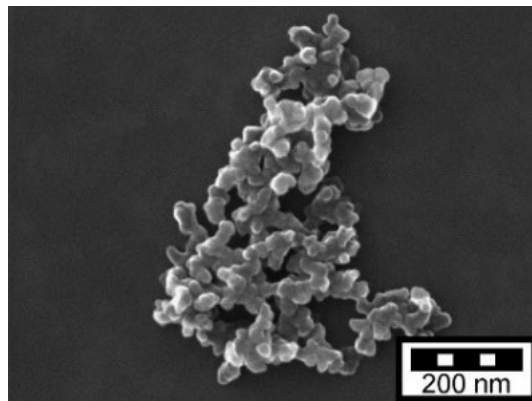


Figure 5: A SEM image of a fumed nano SAS

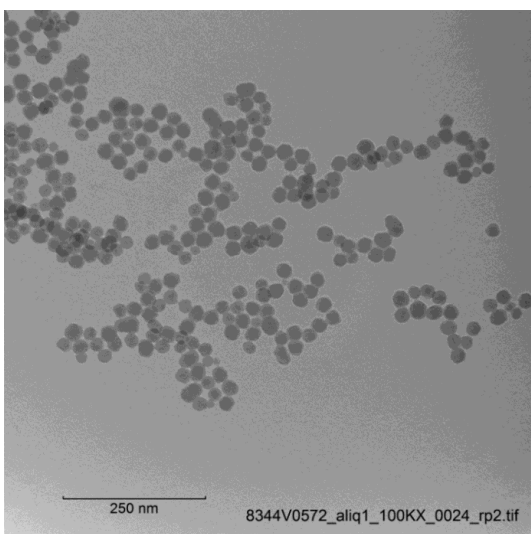


Figure 3: A TEM image of a colloidal nano SAS

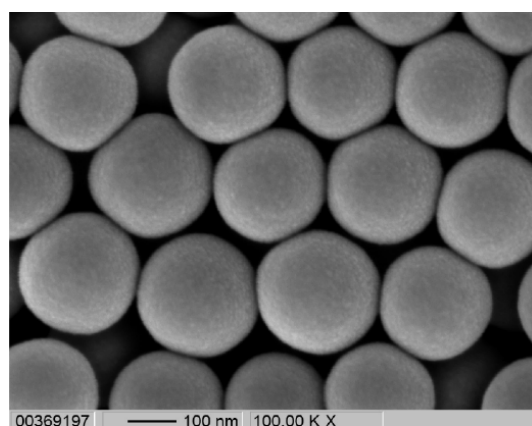


Figure 6: A SEM image of a colloidal bulk SAS